Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed October 14, 2009. Currently, claims 53-80 remain pending of which claims 72-77 were previously withdrawn. Claims 53-71 and 78-81 have been rejected. Applicant notes that there is no currently pending claim 81. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 112

Claim 63 was rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement. It was asserted that the specification does not describe the first catheter includes an infusion port within the proximal end region in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention. Applicant respectfully disagrees. As described at page 7, lines 11-15:

> In still another embodiment, the guiding catheter includes an infusion port proximal to the occlusion balloon. The port communicates with an infusion lumen in the catheter and is adapted for infusion of fluid or pharmaceutical agents. Using the infusion port, the dosage of pharmaceutical agent required to achieve local effect can be reduced compared to administration by systemic route.

some embodiments of the catheter may have lumens communicating with a proximal end and a port proximal to the occlusion balloon.

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient"). (MPEP 2163. II., 3., (a).) The skilled artisan would understand that the proximal end region of the infusion lumen must have an infusion port for the introduction of fluids in order to be configured for the passage of perfusing fluid such as pharmaceutical agents which are supplied outside of the body. Such an infusion port in the proximal end region would be proximal the balloon.

Applicant respectfully requests that the rejection be withdrawn.

Claim 78 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention indicating insufficient antecedent basis for the limitation "the outer catheter shaft". Applicant has amended claim 78 to further prosecution of this case. As such, this rejection is considered moot. Applicant notes that MPEP 2173.05(e) indicates that: "Examiner should suggest corrections to antecedent problems."

Claim Rejections – 35 USC § 103

Claims 53-58, 60-65, and 68-71 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 99/22673), hereinafter Gray, in view of Patel (U.S. Patent No. 4,832,028). After careful review, Applicant must respectfully traverse this rejection. Although the Examiner has not pointed out how the claims are being interpreted as suggested under MPEP 2173.06, Applicants will attempt to respond in a manner consistent with the rejections found in the Office Action mailed October 14, 2009 to further prosecution.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As acknowledged by the Examiner, nowhere does Gray appear to disclose a first catheter shaft, or an outer catheter shaft, with a balloon coupled thereto. Furthermore, nowhere does Gray appear to disclose, "wherein the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded". Further still, while Gray appears to disclose a stent which is capable of expanding radially, Gray does not appear to teach that the stent "is self-expanding and configured to be deployed from a position between the distal end of the first catheter shaft and the filter" as recited in claim 53 or "a self-expanding stent coupled to the inner catheter shaft" as recited in claim 68. Nothing in Gray appears to indicate that the stent (not shown) is anything other than passively expanded. Although the

Examiner has repeated the assertion that a self-expanding stent is known in the art and that such a stent could have been delivered from a sheath not present in Gray, there is no such sheath in the disclosure of Gray and the outer catheter of Patel stops well short of the stenosis 31 of Patel and so would not appear to be suited to serve as the sheath which should be deposited by the balloon 33 as shown in Fig. 2. Thus, nowhere does Patel appear to remedy the shortcomings of Gray with respect to the self-expanding stent and the combination does not appear to be capable of delivering such a stent to the stenosis. If the asymmetric lumen of the catheter of Patel is said to correspond to those sheaths known in the art, it would appear to deposit any self-expanding stent contained therein in an inappropriate location. Applicant does not traverse the assertion that self-expanding stents are known in the art, only the assertion that the combination of Gray and Patel either teaches such a self-expanding stent or that the combination would be suitable to deliver a self-expanding stent to an appropriate location within the stenosed vessel given the structures and operating principles associated with the two references.

Patel does not appear to disclose a stent, much less a self-expanding stent, or a stent configured to be deployed from a position between the distal end of the first catheter shaft and the filter. Patel, the only reference said to have both an inner and outer catheters capable of deploying the posited self-expanding stent, has no filter or equivalent structure with respect to which the stent might be positioned upon deployment. The stabilizing outer catheter of Patel is fixed in position relative to the vessel by the associated expanded balloon when the inner catheter bearing the angioplasty balloon is advanced to the stenosis and so would not appear to be capable of being withdrawn in the vicinity of the stenosis to deploy a self-expanding stent in a position well distal of its most distal advancement.

The Examiner characterizes the catheter of Patel as having an "end region extending from port 27 to the distal tip of the catheter" and arbitrarily asserts that this allows the portion proximal of the balloon to be considered a "proximal end region" despite the absence of an "end" in the vicinity of the port as that term is understood and commonly used. The parsing of the catheter of Patel to create an "end", much less a proximal end, at an arbitrary point within the uniform and uninterrupted distal portion of a continuous catheter appears to be inappropriate and inconsistent with the disclosure of

Patel; the usage of the term in the pending application to indicate the proximal end of the catheter where pharmaceutical agents might be introduced (page 15, lines 20-22); and the ordinary meaning of the word. [end: n. 1 a : the part of an area that lies at the boundary b (1) : a point that marks the extent of something (2) : the point where something ceases to exist c : the extreme or last part lengthwise (Merriam-Webster's Online Dictionary, 11th Edition, October 30, 2009)]

The Examiner is reminded that although claims in an application are to be given their broadest reasonable construction, that broadest construction is in light of the specification as interpreted by one of ordinary skill in the art:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). 37 CFR 1.75(d)(1). (Emphasis Added.)

Note that neither 37 CFR nor the MPEP makes provision for a claim to be construed by the Examiner in a manner inconsistent with the specification as the specification would be understood by one of ordinary skill in the art. Similarly, the Examiner is not empowered to supply definitions for terms which are at odds with their ordinary meanings. Explicit guidance is provided at MPEP 2106: "USPTO personnel must always remember to use the perspective of one of ordinary skill in the art."

The improperly narrow interpretation provided by the Examiner appears to have been necessary to allow the catheter shaft to define a perfusion lumen with a flow being supplied at a "proximal end region" as recited in the pending claims since Patel does not appear to have a filter into which debris could be flushed and so does not appear to teach a flow originating at the proximal end of the catheter, other than that required to inflate the balloon. Patel appears to lack, for example, a hemostatic valve at the proximal end of the catheter for the introduction of material and to prevent a proximal fluid discharge.

Once the Examiner has chosen to rely upon a perfusion fluid (oxygenated blood) running from port 27 through a perfusion lumen and out of the distal end of the catheter of Patel to provide "a perfusion lumen configured for the passage of perfusing fluid supplied at the proximal end region therethrough so as to flush embolic debris into the

filter", a further difficulty arises in that the pending claims also require "wherein the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded"; however Patel appears to teach and to rely explicitly upon continuous flow of blood past the positioning balloon 25.

The balloon of Patel explicitly does not stop fluid from outside the outer catheter shaft proximal to the balloon from flowing distally past the balloon when the balloon is expanded. Indeed, the function of the balloon of Patel, that of engaging the inner surface of the vessel to avoid displacement of the catheter to which it is attached, does not inherently or necessarily prevent the balloon from allowing significant blood to bypass the balloon through gaps between the balloon and the vessel wall.

> "Side holes in the guiding catheter allow blood to bypass the inflated balloon on the guiding catheter. Otherwise, the inflated balloon would obstruct the flow of blood to the coronary artery." [Col. 1, lines 53-56.]
>
> and
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> "The guiding catheter 11 also has a side hole 27 above the balloon 25. The side hole 27 passes through the guiding catheter 11 to allow blood to flow from the aorta 13, through the side hole 27, and out the tip 21 of the guiding catheter 11." [Col. 2, lines 19-23.]
>
> and
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> "Blood flow is thus not restricted by the inflated balloon 25 on the guiding catheter." (Col. 2, lines 67-68.)
>
> and
>
> "Further, although balloon 25 on the guiding catheter 11 contacts the inner surface of the coronary artery 19, blood flow is not restricted. Blood is perfused through the side hole 27 in the guiding catheter." (Col. 3, lines 23-27.)

Having asserted that Patel teaches a perfusion fluid (oxygenated blood) running from port 27 through a perfusion lumen and out of the distal end of the catheter of Patel to provide "a perfusion lumen configured for the passage of perfusing fluid supplied at the proximal end region therethrough so as to flush embolic debris into the filter", the Examiner must also simultaneously assert that blood outside of the catheter of Patel

proximal to the balloon does not flow "distally past the distal region of the shaft when the balloon is expanded". This requires the Examiner to ignore the plain language of the claims, which states that the combination of the catheter and the balloon prevents blood in one region from flowing past the distal section and into a second region, and to read a limitation as to the path traveled, presumably solely around the balloon, which does exist into the claim. This also requires ignoring the repeated teaching of Patel that blood in the flow present proximal of the balloon is not restricted by the balloon and flows out the tip 21 of the guiding catheter 11.

Given the Examiner's earlier interpretation of Patel above, in which oxygenated blood from the vicinity of port 27 of Patel does not appear to flow past the balloon and out the distal end of the catheter of Patel, there would appear to be no perfusion lumen configured for the passage of fluid so as to flush embolic debris into the filter of Gray were the catheter of Patel to be combined with the filter of Gray. Accordingly, at least one of these apparently mutually contradictory interpretations of Patel appears to fail to provide the claim element which Patel is asserted to supply and so the combination of Gray in view of Patel does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness as applied to claims 53 and 68.

Regarding claim 68, the Examiner correctly notes that the catheter and balloon recited in claim 68 are configured to stop fluid from outside the outer catheter shaft proximal to the balloon from flowing distally past the balloon; however the Examiner incorrectly assumes that the claim states that "flowing distally past the balloon" requires that the fluid in question must flow around the exterior of the balloon rather than through the interior of the balloon in order to flow distally past the balloon. The claim imposes no such limitation, but rather simply states that the flow must be stopped by the combination of the catheter and the balloon. A leak through the catheter is equivalent to a leak around the balloon for the purpose of not stopping a flow past the balloon.

With respect to the infusion ports of claim 63 and 64, the Examiner is correct that the mere presence of an infusion port within the proximal end region which provides a fluid flow within the catheter from the proximal end to the distal end does not exclude the prevention of fluid from outside the catheter from flowing past the distal region even if that fluid is blood introduced from outside the body so long as it does not originate

outside the catheter and proximal of the balloon. There is no apparent conflict among these claims.

The Examiner notes that there is a lumen of the guiding catheter taught by Patel running from the proximal end of the catheter shaft to the distal end of the catheter, thereby apparently abandoning the earlier relied upon location of the proximal "end" within the distal region, and asserts without support that the lumen is capable of allowing fluid to flow from the proximal end to the distal end to flush embolic debris into the filter. While this may possibly be the case, Patel does not appear to teach that lumen 41 is configured for the passage of a perfusing fluid, but instead indicates that lumen 41 is the conduit through which the dilating catheter 29 is passed. No other utility appears to be asserted by Patel in the two instances in which that lumen is discussed.

Since Patel does not have a filter into which a fluid might flush debris, there is no reason to assume that the lumen is necessarily configured to carry a flushing fluid. The lumen may, for example, include seals to prevent backflow along the inner catheter. The lumen 43 of the catheter of Patel which does appear to be the only lumen configured to carry fluid appears to terminate in the balloon and does not appear capable of allowing fluid to flow beyond the distal end of the catheter. Lumen 41 does not appear to be inherently configured for the passage of perfusing fluid for the reason that the catheter of Patel does not appear to articulate a purpose for such a perfusing fluid. Within Patel the term perfused and perfusion appear to be restricted to the introduction of blood into the catheter through port 27 and appear in no other context. Infusion does not appear.

If blood does pass the distal region of Patel by traveling through the lumen of the catheter as described by Patel, then the balloon and the outer catheter shaft do not appear to be configured to stop fluid from outside the outer catheter shaft proximal to the balloon from flowing distally past the balloon when the balloon is expanded. As claimed, the blood in question may not pass outside of the balloon and it may pass inside of the balloon (through the catheter). If instead blood does not pass the distal region of Patel as also asserted by the Examiner, then Patel appears to fail to define a perfusion lumen therein that is "configured for perfusing fluid therethrough from an infusion port proximate the proximal end of the shaft so as to flush embolic debris into the filter". In either event, port 27 does not appear to provide "an infusion port proximate the proximal

end of the shaft" as recited in claim 68. Even if there were to be a supplied fluid flow from the proximal end through lumen 41, with an attendant exit flow out of port 27, this would appear to preclude the entrance of blood through the port 27 of sufficient volume to ensure that blood flow is not restricted, thereby rendering the catheter of Patel unsatisfactory for its intended purpose of ensuring unrestricted blood flow through the port and so beyond the distal region which includes the positioning balloon. (See MPEP § 2143.01 Part V.)

For at least the reasons discussed above, Gray in view of Patel does not appear to teach all the claim limitations of independent claims 53 and 68, as is required to establish a *prima facie* case of obviousness. Applicant respectfully requests that the rejections be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 54-58, 60-65, and 69-71, which depend from nonobvious independent claims 53 and 68, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 59, 66, 67, and 78-80, there being no currently pending claim 81, were rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Patel as applied to claims 53 and 56, and further in view of Dubrul (U.S. Patent No. 6,258,115). After careful review, Applicant must respectfully traverse this rejection.

Initially, it should be noted that claims 79 and 80 do not depend from claims 53 and 56 and so it is unclear how Dubrul is being applied to them. Although Dubrul does appear to teach a stent which could be enlarged using thermal energy, it is unclear that thermal expansion is equivalent to self-expansion. In any event, the arguable addition of an enlargable stent to the disclosures of Gray and Patel does not appear to overcome the deficiencies of those references as applied to nonobvious independent claim 53 as discussed in detail above.

Accordingly claims 59, 66, 67, and 78, which depend from nonobvious independent claim 53, are also believed to be nonobvious and Applicant respectfully

requests that the rejections be withdrawn.

Claims 79 and 80, which depend from nonobvious claim 68, are also believed to be nonobvious and Applicant respectfully requests that the rejections be withdrawn, Dubrul not having been applied to independent claim 68.

Double Patenting

A patent granted on a continuation, divisional, or continuation-in-part application that was filed on or after June 8, 1995, will have a term which ends twenty years from the filing date of earliest application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c), regardless of whether the application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c) was filed prior to June 8, 1995.

The pending application claims benefit as a continuation of the earliest filed member of the family, U.S. Patent 6,168, 579, and absent any extension of term, will thus expire coterminally with that patent. No terminal disclaimer is believed to be necessary.

In the Response to Arguments, the Examiner repeats the earlier assertion that the diversion of a flow outside the catheter of Patel to a path which passes through the balloon in the lumen of the catheter is does not meet the limitation of the claim. This is believed to be an incorrect reading of the claim which only states that combination of the balloon and the catheter combined are configured to stop fluid initially located outside of the catheter shaft and proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded. The limitation simply states that fluid in one location may not flow in another location. The path taken is immaterial to whether the catheter and the balloon together stop the flow from occurring. The Examiner's interpretation would appear to more nearly apply were the claim to read "wherein the balloon is configured to stop fluid outside of the first catheter from flowing distally around the balloon". It does not. Instead, Patel appears to insist that a flow occurs from a region outside the catheter and proximal of the balloon to continue beyond the distal tip of the anchoring catheter as it must to maintain perfusion of the tissue which depends upon that flow.

As noted above, the mere existence of an infusion port in the region in question

does not preclude the possibility that the device has a configuration in which the flow is stopped. So long as one such configuration exists, the claim limitation is met. For example, as suggested by the Examiner, a distal flow within a catheter may have sufficient volume that inflow through a side port does not occur and so the various limitations would be met. Patel does not appear to disclose such a flow and to introduce such a flow would appear to prevent the catheter of Patel from functioning as intended to provide a continuous flow of blood around the obstruction introduced by the anchoring balloon. The Examiner is correct that a perfusion port located in the position of port 27 of Patel, in combination with a catheter having a perfusion configured for the passage of perfusing fluid supplied at the proximal end thereof does not render a catheter lumen incapable of allowing fluid to pass from the proximal end of the catheter to the distal end of the catheter; however the disclosure of Patel does not provide such a flow from the proximal end of the catheter and the flow described by the Examiner would appear to block the inflow of blood upon which the catheter of Patel depends for its continuous bypass function. As noted earlier, the catheter of Patel does not appear to be capable of simultaneously blocking and ensuring a flow into the port 27 and out the distal end of the catheter.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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